

Appendix 1

(Ranked by FY 1999 Total Sponsored Research Expenditures)

Attachment E

U.S. UNIVERSITIES:	Name of Institution	Year 0.5 Prof. FTE Devoted to Tech. Transfer	FY 1999 Total Sponsored Research Expenditures	FY 1999 Invention Disclosures Received	FY 1999 Total U.S. Patent Applications Filed	FY 1999 Licenses & Options Executed	FY 1999 Adjusted (*) Gross License Income Received	FY 1999 Licenses & Options Yielding License Income	FY 1999 Legal Fees Expended	FY 1999 Legal Fees Reimbursed	FY 1999 U.S. Patents Issued	FY 1999 Start-up Companies Formed
	Univ. of California System	1979	\$1,864,901,000	818	670	219	\$74,133,000	715	\$12,500,000	\$7,900,000	281	13
	Johns Hopkins University	1973	\$1,010,088,334	250	256	106	\$10,353,453	137	\$3,288,453	\$1,344,461	111	7
	Massachusetts Inst. of Technology (MIT)	1940	\$725,600,000	381	341	95	\$16,131,334	346	\$5,933,157	\$2,284,627	154	17
	Univ. of Michigan	1982	\$499,722,000	158	147	42	\$3,472,671	90	\$2,764,309	\$1,116,081	56	2
	Univ. of Washington/Wash. Res. Fdn.	1983	\$479,654,994	226	114	115	\$27,878,900	185	\$1,338,024	\$457,327	36	N.A.
	Univ. of Pennsylvania	1986	\$477,000,000	244	151	57	\$2,984,000	55	\$1,677,000	\$1,399,000	82	6
	W.A.R.F./Univ. of Wisconsin-Madison	1925	\$421,600,000	278	162	106	\$18,011,400	191	\$2,850,000	\$177,000	79	4
	Univ. of Minnesota	1957	\$417,556,493	219	99	71	\$5,662,088	153	\$1,940,733	\$1,091,233	55	5
	Stanford University	1970	\$417,037,000	236	237	147	\$27,699,355	339	\$2,674,594	\$958,879	90	19
	North Carolina State University	1984	\$413,369,278	148	62	83	\$7,761,000	60	\$936,145	\$735,545	30	8
	SUNY Research Foundation	1979	\$405,238,284	201	-123	46	\$13,538,619	149	\$1,671,656	\$133,999	53	3
	Texas A&M University System	1992	\$402,203,000	145	85	53	\$5,180,510	155	\$879,302	\$457,362	19	0
	Harvard University	1977	\$401,849,500	109	186	48	\$9,886,404	166	\$3,150,532	\$2,298,884	72	2
	Penn State University	1989	\$393,462,000	188	231	40	\$2,830,448	64	\$897,517	\$458,299	46	3
	Cornell Research Fdn., Inc.	1979	\$376,784,000	172	147	150	\$6,070,000	199	\$2,900,000	\$2,200,000	70	4
	Univ. of Illinois, Urbana, Champaign	1993	\$358,247,000	104	53	39	\$2,856,207	84	\$578,089	\$8,116	14	4
	Duke University	N.A.	\$334,505,814	115	111	41	\$1,566,195	73	\$1,241,331	\$565,312	40	2
	Washington University	1985	\$333,196,000	104	78	114	\$6,999,971	107	\$1,168,144	\$939,485	39	4
	Univ. of Colorado	1993	\$331,579,000	79	63	10	\$3,127,303	10	\$329,300	\$26,778	27	1
	Univ. of Arizona	1988	\$320,244,777	97	40	11	\$314,299	31	\$118,494	\$116,028	8	3
	Yale University	1982	\$315,933,000	70	110	23	\$40,695,606	28	\$1,186,852	\$322,924	37	3
	Univ. of Pittsburgh	1992	\$311,200,000	107	70	16	\$608,851	23	\$1,636,874	\$421,008	30	3
	Univ. of Florida	1983	\$280,408,217	136	127	10	\$21,649,577	45	\$2,937,299	\$791,876	58	2
	Columbia University	1982	\$279,275,674	182	109	98	\$89,159,556	212	\$4,030,556	\$1,152,913	77	5
	Univ. of Iowa Research Fdn.	1975	\$259,514,262	79	83	21	\$3,464,565	80	\$1,530,469	\$728,514	32	2
	Univ. of Texas at Austin	1988	\$258,172,000	81	49	31	\$1,929,390	24	\$553,213	\$330,953	17	1
	Ohio State University	1990	\$257,950,000	100	35	26	\$1,626,000	34	\$345,000	\$112,000	18	0
	Univ. of Southern California	1971	\$254,811,651	156	101	57	\$450,568	55	\$650,668	\$190,757	13	4
	Purdue Research Foundation	1988	\$253,018,364	102	81	76	\$2,149,000	201	\$1,070,000	\$548,000	24	4

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Baylor College of Medicine	1983	\$239,000,000	89	39	35	\$12,280,879	110	\$621,363	\$117,324	25	0
Univ. of Georgia	1979	\$237,493,000	72	44	32	\$3,208,427	64	\$878,682	\$681,680	21	5
Northwestern University	N.A.	\$236,668,615	80	71	14	\$2,758,450	38	\$416,895	\$264,301	35	0
Georgia Institute of Technology	1990	\$223,641,675	127	143	18	\$2,038,078	46	\$833,832	\$106,136	23	3
Univ. of Missouri System	1987	\$212,238,803	62	37	16	\$1,544,985	21	\$399,971	\$231,806	22	1
Indiana University (ARIT)	1991	\$209,154,093	59	38	14	\$1,040,092	39	\$632,995	\$201,458	18	1
Michigan State University	1992	\$207,912,000	85	82	33	\$2,711,867	48	\$1,187,038	\$245,446	63	1
Univ. of Massachusetts, All Campuses	1995	\$206,382,231	112	N.A.	19	\$4,105,000	41	N.A.	N.A.	32	2
Emory University	1985	\$205,600,000	89	50	13	\$15,257,565	35	\$915,425	\$500,948	44	4
Univ. of North Carolina/Chapel Hill	1985	\$198,081,333	116	74	70	\$1,696,786	47	\$956,393	\$564,159	41	0
Univ. of Virginia Patents Fdn'ta.	1977	\$197,046,500	154	153	25	\$4,185,446	62	\$569,024	\$179,877	23	6
Iowa State University	1935	\$186,700,000	160	106	163	\$1,812,870	298	\$854,852	\$335,317	49	2
Univ. of Rochester	1980	\$185,488,000	85	53	5	\$2,994,170	17	\$729,000	\$33,000	14	1
Univ. of Maryland, College Park	1987	\$185,036,200	84	113	61	\$968,144	109	\$430,190	\$196,120	12	3
Univ. of Utah	1968	\$182,753,466	172	98	25	\$3,257,026	58	\$939,807	\$256,946	40	8
Univ. of Texas Southwestern Med. Ctr.	1990	\$179,709,069	80	63	23	\$4,856,751	57	\$996,890	\$422,397	27	1
Case Western Reserve University	1986	\$176,519,336	59	37	10	\$505,192	16	\$284,243	\$24,463	17	3
Univ. of Miami	1989	\$175,600,000	27	9	9	\$432,937	22	\$211,404	\$66,344	8	0
Univ. of Illinois at Chicago	1985	\$175,093,000	61	35	20	\$1,839,290	45	\$355,451	\$209,792	13	2
Univ. of Alabama/Birmingham	1987	\$171,831,840	121	113	40	\$1,568,587	58	\$804,313	\$150,935	24	2
Univ. of Tennessee Research Corp.	1983	\$170,896,000	75	54	7	\$602,053	24	\$612,123	\$81,813	17	1
Virginia Tech Intellectual Properties, Inc.	1985	\$169,250,000	65	58	41	\$1,328,343	74	\$180,830	\$42,396	37	3
Carnegie Mellon University	1992	\$167,675,342	104	36	23	\$5,892,284	51	\$1,183,217	\$35,600	30	5
Univ. of Kansas	1994	\$167,575,000	67	22	7	\$885,000	39	\$129,000	\$65,000	10	1
Rutgers, The State University of NJ	1989	\$165,872,573	112	103	60	\$4,304,616	73	\$1,026,345	\$801,421	31	3
Vanderbilt University	1990	\$165,200,000	87	51	31	\$1,100,579	44	\$440,251	\$216,718	17	2
Univ. of Chicago-ARCH Dev. Corp.	1986	\$162,805,000	65	74	14	\$1,868,392	40	\$1,635,106	\$746,700	33	1
Univ. of South Florida	1990	\$161,300,000	48	53	13	\$490,408	18	\$385,579	\$84,444	24	8
Univ. of Hawaii	1987	\$151,809,406	41	36	0	\$171,877	19	\$235,501	\$17,269	11	0

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		Total Sponsored Research Expenditures	FY 1999 Invention Disclosures Received					Legal Fees Expended	Legal Fees Reimbursed		
California Institute of Technology	1978	\$150,000,000	143	212	21	\$6,500,000	35	\$1,150,000	\$33,000	62	7
New York University	1989	\$149,000,000	50	N.A.	N.A.	\$10,700,000	18	\$1,000,000	\$700,000	30	2
Univ. of New Mexico/Sci. & Tech. Corp.	1995	\$148,600,000	47	53	3	\$400,200	9	\$374,500	\$85,200	15	2
Colorado State University	1970	\$147,664,283	30	17	9	\$386,990	18	\$98,177	\$32,258	13	4
Wayne State University	1988	\$147,000,000	39	18	3	\$458,000	12	\$106,000	\$15,000	18	1
Oregon State University	1980	\$145,665,138	38	25	17	\$825,283	45	\$201,382	\$117,569	6	1
Boston University	1976	\$142,515,956	56	52	17	\$763,095	18	\$764,966	\$422,999	22	7
Florida State University	1996	\$132,664,855	23	15	8	\$57,313,014	14	\$160,282	\$104,883	5	1
Univ. of Maryland, Baltimore	1989	\$131,484,606	62	44	7	\$116,681	16	\$281,886	\$93,120	12	2
Univ. of Nebraska-Lincoln	1996	\$131,046,000	32	28	8	\$796,894	24	\$253,173	\$0	9	2
Mount Sinai School of Medicine of NYU	1991	\$123,404,735	36	35	12	\$1,012,061	14	\$781,672	\$51,168	9	0
Univ. of Cincinnati	1983	\$115,025,000	47	36	15	\$3,905,945	16	\$145,033	\$29,687	6	4
Virginia Commonwealth University	1994	\$113,000,000	88	68	17	\$459,200	21	\$131,124	\$63,005	14	3
Univ. of Texas Houston Hlth. Sci. Ctr.	1985	\$107,035,788	20	12	8	\$343,050	9	\$223,230	\$0	6	0
Univ. of Connecticut	1987	\$105,800,000	45	32	12	\$481,134	10	\$304,600	\$6,000	11	2
Princeton University	1987	\$102,000,000	60	61	14	\$1,480,000	20	\$1,650,000	\$1,265,000	26	2
Clemson University	1987	\$99,340,766	29	7	7	\$4,648,141	10	\$72,274	\$0	2	1
Tufts University	1978	\$98,567,533	51	32	12	\$506,149	21	\$625,216	\$299,375	11	0
Oklahoma State University	1995	\$88,900,000	19	9	1	\$154,946	7	\$141,088	\$52,726	4	0
Tulane University	1985	\$87,324,000	13	17	9	\$7,572,483	19	\$235,000	\$130,215	7	0
Oregon Health Sciences University	1989	\$86,822,525	32	45	11	\$291,131	32	\$359,302	\$187,466	15	1
Univ. of Oklahoma-All Campuses	1984	\$85,584,836	30	45	6	\$110,265	7	\$281,455	\$181,981	8	2
Thomas Jefferson University	1984	\$85,400,000	87	80	17	\$742,515	24	\$338,970	\$91,867	27	1
Univ. of Texas Medical Branch	1988	\$85,000,000	30	38	4	\$108,857	10	\$376,655	\$258,549	21	0
Univ. of Kentucky Research Fdn.	1984	\$83,743,077	65	32	9	\$2,496,786	N.A.	\$520,270	\$63,016	24	2
Medical Univ. of South Carolina	N.A.	\$81,246,129	40	24	5	\$121,627	11	\$272,517	\$69,718	8	3
Dartmouth College	1985	\$81,055,083	18	26	7	\$491,302	47	\$173,977	\$117,601	20	0
Auburn University	1988	\$80,544,000	25	13	5	\$186,738	6	\$213,994	\$53,200	12	0
Utah State University	1987	\$80,539,784	27	7	4	\$227,929	15	\$84,884	\$16,634	6	1

AUTM Licensing Survey: SELECTED FACTS & FIGURES FOR FISCAL YEAR (FY) 1999

FY 1999 Survey Summary 38

(Ranked by FY 1999 Total Sponsored Research Expenditures)

Attachment E

U.S. UNIVERSITIES:	Name of Institution	Year 0.5 Prof. FTE Devoted to Tech. Transfer	FY 1999 Total Sponsored Research Expenditures	FY 1999 Invention Disclosures Received	FY 1999 Total U.S. Patent Applications Filed	FY 1999 Licenses & Options Executed	FY 1999 Adjusted (*) Gross License Income Received	FY 1999 Licenses & Options Yielding License Income	FY 1999 Legal Fees Expended	FY 1999 Legal Fees Reimbursed	FY 1999 U.S. Patents Issued	FY 1999 Start-up Companies Formed
	Univ. of Texas Hlth Sci Ctr San Antonio	1990	\$80,020,875	21	41	14	\$3,660,638	32	\$516,571	\$38,768	13	0
	Wake Forest University	1985	\$78,351,866	36	19	6	\$2,788,987	9	\$798,320	\$130,239	3	1
	Brown University Research Fndn.	1983	\$76,330,000	40	36	4	\$1,009,516	13	\$157,041	\$93,222	17	1
	Univ. of South Carolina	1993	\$69,819,000	36	26	7	\$175,187	12	\$88,264	\$10,813	4	0
	Univ. of Delaware	1997	\$64,872,678	20	29	4	\$470,303	8	\$122,683	\$7,910	3	2
	Univ. of Arkansas, Fayetteville	1990	\$63,110,717	26	21	2	\$259,883	21	\$187,862	\$38,423	13	1
	New Mexico State University	1990	\$63,037,606	12	10	3	\$1,792	3	\$115,770	\$17,031	2	0
	West Virginia University	1999	\$62,000,000	9	3	1	\$41,800	5	\$83,500	\$0	2	0
	Arizona State University	1985	\$60,091,584	49	47	11	\$1,274,145	18	\$547,472	\$172,444	12	1
	Univ. of New Hampshire	1997	\$60,015,544	6	5	6	\$34,696	5	\$14,336	\$0	0	0
	Univ. of Oregon	1992	\$58,616,598	9	11	10	\$232,000	20	\$86,858	\$90,000	5	1
	Univ. of Louisville	1996	\$53,258,000	30	9	3	\$48,632	4	\$30,869	N.A.	2	1
	Kansas State University Research Fndn.	1942	\$52,597,214	28	16	7	\$258,063	31	\$216,370	\$135,589	12	2
	Univ. of Vermont	1998	\$52,500,000	25	11	6	\$338,000	3	\$182,000	\$88,000	2	0
	Idaho Research Fndn./Univ. of Idaho	1986	\$50,345,178	18	7	2	\$140,500	6	\$299,413	\$199,388	3	0
	Montana State University	1980	\$49,741,400	15	12	7	\$243,700	18	\$203,630	\$159,890	7	1
	Temple University	1986	\$45,456,670	19	N.A.	5	\$493,947	16	\$213,892	\$0	N.A.	0
	North Dakota State University	1995	\$44,696,000	23	6	7	\$1,059,797	38	\$93,041	\$6,596	4	0
	Rice University	1998	\$44,500,000	20	33	8	\$21,000	4	\$117,000	\$9,000	1	1
	Louisiana State University, Agric. Ctr.	1989	\$44,318,252	17	7	7	\$1,091,787	17	\$153,265	N.A.	3	1
	Univ. of North Dakota	N.A.	\$43,131,073	2	1	0	\$0	0	\$8,578	\$0	0	0
	Brandeis University	1982	\$42,666,882	17	18	6	\$120,126	21	\$184,820	\$180,411	9	3
	New Jersey Institute of Technology	1990	\$42,500,000	35	8	2	\$22,500	3	\$175,000	\$0	4	0
	Univ. of Houston	1996	\$42,002,331	40	7	5	\$120,831	8	\$294,601	\$71,072	5	0
	Univ. of Maine	N.A.	\$41,453,000	6	3	2	\$0	0	\$30,301	\$0	4	0
	Univ. of Rhode Island	1991	\$41,400,000	12	7	11	\$823,385	10	\$123,447	\$666	3	0
	San Diego State University	1998	\$40,624,000	7	3	4	\$82,000	2	\$50,000	\$0	1	2
	Syracuse University	1989	\$39,500,000	10	4	1	\$112,529	16	\$181,628	\$129,483	5	0
	Univ. of Dayton	1984	\$37,039,132	28	9	2	\$567,535	5	\$246,160	\$129,197	8	1

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George Mason University	1996	\$32,376,000	13	11	0	\$753	1	\$10,360	\$0	3	0
Loyola University Medical Center	N.A.	\$29,778,103	4	3	10	\$507,500	10	\$86,252	\$0	0	0
Michigan Technological University	1988	\$28,073,860	20	11	11	\$222,272	18	\$174,275	\$2,500	2	0
St. Louis University	1998	\$27,817,000	19	15	3	\$788,472	22	\$160,157	\$83,590	6	0
Univ. of South Alabama	1995	\$27,252,916	5	11	0	\$7,178	3	\$131,031	\$0	6	0
Creighton University	1992	\$25,700,000	17	3	2	\$123,717	4	\$27,779	\$0	2	0
Lehigh University	N.A.	\$25,312,458	N.A.	N.A.	N.A.	\$117,661	7	\$26,000	\$0	N.A.	N.A.
Southern Illinois Univ./Carbondale	1993	\$23,655,654	15	6	6	\$48,245	9	\$149,877	\$30,163	N.A.	0
Kent State University	1989	\$23,472,249	12	5	3	\$147,159	7	\$221,087	\$119,488	4	1
Univ. of Montana	1995	\$22,996,357	5	2	3	\$67,000	4	\$54,422	\$0	2	0
New York Medical College	1994	\$22,821,758	16	3	3	\$87,589	8	\$43,133	\$25,030	3	2
Wright State University	N.A.	\$22,753,000	2	1	4	\$18,525	6	\$6,254	\$0	1	0
Univ. of New Orleans	1999	\$22,297,000	6	6	1	\$13,770	2	\$39,881	\$5,000	2	0
Univ. of Maryland, Baltimore County	1994	\$21,854,000	26	9	1	\$39,117	2	\$100,525	\$0	6	0
Univ. of Maryland Biotech Institute	1995	\$20,387,312	17	14	4	\$335,000	2	\$367,328	N.A.	4	0
Brigham Young University	1986	\$17,226,876	71	12	21	\$3,961,971	51	\$215,310	\$29,633	4	1
Ohio University	1991	\$16,492,896	13	8	0	\$617,805	3	\$174,515	\$119,272	4	0
Univ. of Northern Iowa	1998	\$13,148,015	0	2	0	\$1,268	1	\$13,364	\$0	2	0
Medical College of Ohio	1983	\$11,895,179	7	2	0	\$22,991	6	\$75,664	\$21,701	6	0
Portland State University	N.A.	\$11,735,117	3	0	0	\$0	0	\$0	\$0	0	0
California State Polytechnic University	1999	\$11,575,000	1	2	2	\$10,000	2	\$47,000	\$0	1	0
Univ. of Akron	1995	\$10,193,500	29	20	7	\$244,056	15	N.A.	N.A.	11	1
East Carolina University	1995	\$8,360,000	10	6	1	\$76,000	0	\$46,836	\$3,984	2	0
TOTAL U.S. UNIVERSITIES		\$23,565,568,068	10,052	7,612	3,295	\$641,000,108	6,663	\$100,438,800	\$47,438,911	3,079	275

* Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).

Attachment E

Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).

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CANADIAN INSTITUTIONS:

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Univ. of Toronto	1980	\$209,121,012	90	25	17	\$844,175	21	\$308,452	\$150,997	6	5
Univ. de Montreal	1990	\$133,658,635	37	22	15	\$362,229	16	\$187,347	\$73,738	13	8
McGill University	1990	\$125,454,301	95	N.A.	24	\$539,433	38	\$363,653	\$269,289	17	8
Univ. of Alberta	1987	\$115,918,697	59	47	15	\$2,434,907	20	\$400,699	\$93,718	11	4
Univ. of British Columbia	1984	\$95,341,717	126	95	14	\$788,209	55	\$1,030,188	\$780,024	50	6
UTi, Inc./Univ. of Calgary	1985	\$71,519,412	77	37	29	\$1,871,917	53	\$383,075	\$220,728	15	3
Univ. of Western Ontario	1995	\$60,573,428	29	14	7	\$43,556	16	\$92,421	\$0	4	5
McMaster University	1987	\$53,059,239	29	3	9	\$365,589	13	\$19,904	\$5,707	2	0
Queen's University	1984	\$46,556,737	38	17	8	\$674,660	27	\$307,177	\$192,474	12	0
Hospital for Sick Children Research	1985	\$41,024,364	33	11	24	\$461,031	37	\$205,950	\$43,074	7	2
Univ. of Waterloo	1990	\$38,026,652	8	7	17	\$459,348	56	\$85,779	\$21,718	6	0
Univ. of Manitoba	1983	\$31,192,381	22	39	15	\$969,731	28	\$204,244	\$3,692	7	0
Univ. of Sherbrooke	1986	\$26,921,524	21	4	22	\$2,692,152	54	\$316,921	\$151,670	3	2
Carleton University	1986	\$18,425,175	20	1	2	\$97,698	2	\$13,023	\$1,905	0	1
Simon Fraser University	1985	\$15,601,834	17	15	6	\$556,350	5	\$70,692	\$2,509	5	4
Univ. of Ottawa Heart Institute	1989	\$12,814,423	5	0	0	\$0	0	\$35,038	\$18,023	0	0
Brava Civic Hospital Loeb Res. Inst.	1995	\$10,768,610	5	3	0	\$333,300	2	\$71,865	\$65,000	0	0
Concordia University	1997	\$10,624,157	3	4	1	\$15,130	3	\$7,137	\$0	2	1
cole De Technologie Supérieure	1996	\$3,005,324	3	1	2	\$15,345	1	\$4,711	\$0	0	1
McGill University	1995	\$2,779,608	0	0	0	\$0	0	\$108	\$0	0	0
TOTAL CANADIAN INSTITUTIONS		\$1,122,387,230	717	345	227	\$13,524,768	447	\$4,108,384	\$2,094,266	160	50

Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).

ALL RESPONDENTS:

	FY 1999 Total Sponsored Research Expenditures	FY 1999 Invention Disclosures Received	FY 1999 Total U.S. Patent Applications Filed	FY 1999 Licenses & Options Executed	FY 1999 Adjusted (*) Gross License Income Received	FY 1999 Licenses & Options Yielding License Income	FY 1999 Legal Fees Expended	FY 1999 Legal Fees Reimbursed	FY 1999 U.S. Patents Issued	FY 1999 Start-up Companies Formed
U.S. UNIVERSITIES	\$23,565,568,968	10,052	7,612	3,295	\$641,000,108	6,663	\$100,438,800	\$42,438,911	3,079	275
U.S. HOSPITALS & RESEARCH INSTITUTES	\$2,110,957,455	1,106	801	355	\$150,148,745	957	\$16,360,600	\$7,131,227	398	17
CANADIAN INSTITUTIONS (U.S. S)	\$1,122,387,230	717	345	227	\$13,524,760	447	\$4,108,384	\$2,094,266	160	50
PATENT MANAGEMENT FIRMS	N.A.	449	44	37	\$57,662,276	241	\$128,887	\$0	24	2
TOTAL ALL RESPONDENTS	\$26,798,912,753	12,324	8,802	3,914	\$862,335,889	8,308	\$121,036,671	\$51,664,404	3,661	344

* Reports prior to FY 1998 reflect Gross License Income Received (see footnote x).

Appendix 2



COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 320, Washington, D.C. 20005

(202) 289-6655/(202) 289-6698 (FAX)

June 5, 2001

Dr. Wendy Baldwin
Deputy Director
Extramural Research
National Institutes of Health
Building 1, Room 114
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Baldwin:

As you requested, we asked COGR member universities that receive substantial funding from HHS for information about their use of royalty returns from intellectual property. The results confirm that relatively few universities derive substantial revenues from royalty returns. They also confirm that universities are reinvesting their share of royalty returns for a wide variety of research and educational purposes, in furtherance of the objectives of the Bayh-Dole Act.

Key points are summarized below, followed by more detailed discussion of the information and data that we received.

Summary

- Institutions reported a wide variety of uses of royalty income. Most frequent uses included research and educational expenses of graduate students, start-up research costs for new or junior faculty, seed money for innovative new projects or initiatives, computer equipment and laboratory facilities renovation.
- A number of universities reported special uses of royalty income including a summer program for female undergraduate students interested in science careers; a technical assistance program providing high technology urban planning and architectural visualization services to inner city communities based on the agricultural extension service model; and a new laboratory building to support the demands of 21st century medical research.
- All the institutions shared royalty revenues received with the inventor(s), consistent with Bayh-Dole Act requirements. Most institutions also distributed a percentage of royalties to the inventor's department and/or research laboratory.
- For all the universities, the percentage of income received from royalties was small as compared to their total federal funding or total sponsored research expenditures. For

at least half of the universities that responded to us, revenues from royalties were low by almost any standard of comparison. For one university, the overall costs of operating its technology management office greatly exceeded its gross royalty revenues. Other responses noted that many universities operate their technology transfer programs at a loss.

- University use of royalty returns is complex and diverse. However, our responses confirm that universities are reinvesting these funds for broad research, education, and associated infrastructure purposes, as contemplated by the Bayh-Dole Act.

Background

We asked COGR member universities for information about the formula used by the university for royalty distribution, the annual university share of royalty income, the uses of royalty income by the university, and any special programs or projects funded by royalty revenues. We received responses from 23 of the top 25 HHS-funded institutions (as identified in the NSF federal funding data for FY99).

It is important to note that these 23 universities do not correspond to the top group of institutions in terms of income received from licensing of intellectual property. In fact, according to the annual licensing survey of the Association of University Technology Managers, Inc. (AUTM), some of them are in the "second 50" in terms of license income received. While some of the universities that responded to us rank very high in the AUTM survey, the overall sample is not biased in terms of the top royalty receiving institutions.

Also of significance is that neither our information nor the AUTM data identify royalty income specifically from drug-related inventions. A substantial amount of the royalties received by the institutions that responded to us may be related to inventions in fields of science and engineering other than the biomedical areas supported by NIH. While universities track and report sponsorship of inventions in accordance with federal requirements, they are not required to separately identify royalty income by individual sponsor, nor is such data reported to AUTM.

The responses we received with regard to distribution of royalty income by the universities and the use(s) made of this income are summarized below.

Distribution Formula

1. All 23 institutions reported that they employed a distribution formula for sharing of the revenues received, consistent with Bayh-Dole Act requirements. The formula varied among the institutions, and in some cases was based on a sliding scale depending on the level of income received. However, in all cases, royalties received from federally-supported inventions were shared between the inventor(s) and the institution, as required by Bayh-Dole. In most cases, a deduction was made from gross revenues to reimburse the university's technology transfer function for direct legal expenses incurred in

patenting or licensing the subject invention. Net revenue then was shared between the inventor and the university, with the university's share reinvested for support of research and education.

2. Most, but not all of the institutions provided us with the specific percentage share paid to the inventor. Most typically, the inventor's share was in the 30-35% range of net income received.
3. The remaining balance of net income was apportioned to the institution. These revenues were redistributed for research and education purposes and for expenses associated with the university's administration of inventions, consistent with the Bayh-Dole guidelines. Most institution formulas provided for distribution of a percentage to the inventor's department and/or research laboratory, and a percentage share to the university. In some cases, the university ultimately returned all or most of its share to the inventor's school, department or laboratory. Some public institutions redistributed a portion of their share to other campuses included in the state university system for research and education purposes. Finally, some institutions allocated a share for administration of the invention or technology management function. Practices varied, with some institutions deducting a portion of gross revenues for this purpose while others allocated a percentage of net.

University Share of Royalty Income

All 23 institutions provided us with data as to royalty income received. However, the data was not provided to us in uniform categories. Some institutions provided us gross revenues only, requiring us to estimate the university share based on the distribution formula used by the institution.

We compared the information provided us with the data reported in the annual AUTM licensing survey. The comparisons presented some difficulties.¹ Nevertheless, in most cases we were able to reconcile the numbers reported to us with the AUTM data reasonably well.

We focused on FY99, since that is the most recent year for which comparable AUTM data are available. It also is the most recent year reported by NSF in its federal funding survey. (It should be noted that the government fiscal year reported by NSF differs from most university fiscal years as reported to us and reflected in the AUTM data). We estimated the total aggregate university share of royalty income received, with payments to inventors and direct legal expenses subtracted; we also subtracted expenses for the administration of the invention or technology management function where paid from gross revenues and not

¹ The AUTM survey reports gross license income received, broken down into several different categories (running royalties, cashed-in equity, and other types). AUTM does not report the distribution of royalty income. In some cases the distributions reported to us by the institutions exceeded the gross income reported to AUTM due to differences in reporting periods (i.e. institutions may distribute in one year income reported to AUTM in a previous year). To fully understand these differences would require much further analysis and comparisons of aggregate data over time, which was beyond the scope of this effort.

allocated as part of the "university share." We estimate that for the 23 reporting institutions, the FY99 aggregate university share was \$208,450,000. For the 23 institutions, this averages to a little over \$9,000,000 per institution. However, only 6 of the 23 reported university revenue in excess of \$9,000,000. If the royalties of these universities are subtracted, the total royalties for the other 17 universities drops to \$54,732,000, with an average share of \$3,220,000.

We compared the revenues received by the 23 institutions with their total Federal obligations for science and engineering reported in the NSF survey data for FY99. The total Federal funding was \$6,620,548,000. The university share of royalty revenue was approximately 3.1% of the total Federal funding. As another comparison, total sponsored research expenditures in FY99 (AUTM survey data, which corresponds more closely to the universities' fiscal years) for these institutions (less several campuses of the University of California, which is reported by AUTM at a consolidated system level) were \$7,260,418,000. The university royalty share was approximately 2.6% of total sponsored research expenditures. These percentages would be even lower if the 6 institutions that received more than \$9M in royalties were excluded.

These data should be considered preliminary estimates in need of considerably more refinement. However, they do suggest that for most universities, royalty income does not represent a significant source of revenue in comparison with Federal funding or total sponsored research expenditures. It is worth noting that even for the University of California System, which in past years typically has led research universities in terms of royalty income generated by its technology transfer program, the royalty income is small as compared with UC research expenditures. In fact, UC's royalty income is approximately 3% of UC research expenditures, which is comparable to the 2.6% of total sponsored research expenditures noted above for the non-UC institutions.

At least half the universities in our sample do not appear to be deriving substantial revenues from royalty income by almost any standard of comparison. For 10 of the institutions the university share of royalty income in FY99 was below \$3M; 2 were in the \$3-4M range; and 2 more in the \$4-5M range. In fact, one university indicated that the overall costs of operating its technology management office and related legal expenses exceeded its gross revenues by a factor of 3 in FY99. The University of California System in their response to us noted, "...although UC is fortunate to have a long established program that has enjoyed considerable success in shepherding the commercialization of many important technologies, at times many of the UC campuses operate their technology transfer programs at a loss." The latter point was reflected in other institution responses as well.

Where universities are deriving more substantial income from their share of royalties, that success often tends to be associated with one particular invention. Also, there appear to be substantial annual fluctuations in income received. We chose to present FY99 data for the reasons indicated above. We also received data for FY00 from most of the institutions. While some institutions reported considerably higher revenues in FY00, for others the

opposite was the case. One institution reported a court settlement in FY00 which quadrupled its gross income from each of the previous two years. One-time occurrences of this sort can result in very large perturbations in the numbers. For these and the other reasons indicated above, this data needs to be approached with caution. Returns of royalties to universities are neither constant nor predictable.

Uses of Royalty Income

Institutions reported a wide variety of uses of royalty income. At the department level these uses tend to cluster in several areas. Those mentioned most frequently are graduate student research-related expenses (e.g. travel), start-up research costs for new or junior faculty, computer equipment and laboratory facilities renovation. Other uses mentioned in more than one response were guest speakers or visiting scholars, postdoctoral research expenses and incentives for faculty retention.

No institution that responded to us appears to systematically track use of royalty returns at the department or laboratory level. Thus we received no information as to the amounts associated with any particular use. Institutions tend to track use of the university share to a greater extent. However, in many cases a significant amount of the university share is redistributed to the school or department level, so information as to the end use of such revenues also is lacking.

A number of institutions mentioned use of all or part of the university share of royalty returns for intramural research competition. Often a special fund is established for this purpose. These are referred to by a variety of names: "Royalty Research Fund," "Science Development Fund," "University Enrichment Fund," "University Research Foundation or Endowment," "Research Incentive Fund," etc. They tend to be geared to support expenses such as start-up costs for new science faculty, seed money for innovative new projects or initiatives, and research expenses for graduate students and postdocs. A number of these funds also provide for graduate fellowship support. With one exception, we did not receive a specific accounting of these particular uses.²

University use of royalty returns clearly is complex and diverse. However, from the responses we received, there seems little doubt that universities are reinvesting these funds in a broad variety of research and educational activities, as contemplated by Bayh-Dole.

² The exception is the Wisconsin Alumni Research Foundation (WARF), perhaps the longest-established of these funds. WARF publishes annual reports that provide detailed information on WARF expenditures, both each year and over time. However, a substantial portion of WARF distributions involve non-royalty income (endowment, etc.); the distribution of royalty income is not broken down separately.

Special Uses

A number of institutions reported using royalty income for special programs or initiatives. An example is a department at Vanderbilt University which used some of its royalty money to help support a program called "Women in Science," a summer program for 4-5 female non-Vanderbilt undergraduate students interested in science careers. The students were placed in university labs and mentored for the summer. The royalty money helped to pay for their housing on campus during this time since few were able to come without some assistance. Columbia University reported a number of special uses of royalty income. These include the Columbia Earth Institute, which seeks to link Columbia's research and educational activities relating to the complex systems of Earth and the urgent need for human action designed to maintain Earth's sustainability, with the activities of like-minded knowledge institutions outside the University; the Digital Media and Information Technology program which comprises a range of activities designed to prepare Columbia to be a national leader in the interactive future; and the Urban Technical Assistance Program, which provides high-technology urban planning and architectural visualization services to neighborhood communities in New York City modeled on the agricultural extension programs of the public land-grant universities. Finally, Yale University has started construction of a new laboratory building to support the demands of 21st century medical research, which has been financed in part by royalty income. The new building will furnish six floors of laboratories for disease oriented research, as well as core research resources and teaching facilities, e.g. a transgenic mouse facility capable of housing up to 74,000 mice, and a new MRI Center. Nine research programs are slated to move into the new building.

Conclusions

There are many limitations to this data, as noted above. It also is important to reiterate that universities are not required to track royalty revenues associated with specific research sponsors. We did not receive any overall data on the share of royalty income associated specifically with NIH-funded inventions. One institution in our sample that has tracked NIH-funded invention royalties is the University of California. In FY99 only 33% of the royalties received by the University of California were derived from inventions associated with NIH-funded research. Our information otherwise does not indicate what percentage of royalties received by a university may be related to NIH support in biomedical areas. In some cases this may represent a substantial portion of revenues; in others the royalties may be more related to information technology or inventions in other fields of science or engineering.³ The data also do not break out inventions related to support from federal vs. non-federal sponsors.

³ At one time AUTM did report the proportion of royalties paid for "life sciences" vs. "physical sciences." For universities the life sciences percentage was in the 80% range. However, the AUTM survey no longer breaks down license income by scientific disciplines, apparently at least in part because of difficulties experienced by institutions in breaking down income data this way. Licensing income associated with the life sciences of course is not necessarily related to NIH funding, and could arise from inventions funded totally or in part by industry sponsors.

Dr. Baldwin
Page 7
June 5, 2001

It also is important to recognize that inventions typically represent the culmination of research conducted over many years, often with the support of multiple sponsors. The primary mission of universities is knowledge, rather than product, creation. For these reasons, it is inherently problematic to attempt to relate specific federal agency investments in university research to returns resulting from that investment in the form of royalties paid on inventions that usually are developed many years later.

Despite the limitations, we believe our data represent reasonable estimates, and that further refinements are unlikely to result in order of magnitude differences. Clearly some universities do much better than others in terms of royalty revenues. For these institutions in particular, we believe our information confirms that the incentives provided by Bayh-Dole are working in the manner intended. Universities are commercializing technology developed with federal support and reinvesting the royalty returns in the research and education enterprise. However, both our information and the AUTM data confirm that relatively few universities are deriving substantial revenues from royalties. The information should help dispel the notion of "windfall profits" being reaped by most universities.

Please let us know if you have questions or would like to discuss any of this information further.

Sincerely,

A handwritten signature in dark ink, reading "Katharina Phillips". The signature is written in a cursive, flowing style.

Katharina Phillips
President

Cc: Dr. Maria Freire

Appendix 3.1, 3.2, 3.3

**United States Public Health Service
Technology Transfer Manual
Chapter No. 200**

PHS Patent Policy

A. PURPOSE

This Manual Chapter sets forth policy for the initiation and prosecution of patents on technologies developed in Public Health Service (PHS) laboratories.

B. BACKGROUND

The primary mission of PHS research laboratories is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner. PHS is cognizant of its role in protecting the public interest as NIH, FDA, and CDC technologies are transferred.

Realization of the considerable anticipated health benefits inherent in PHS conducted and supported biomedical research will depend in large part on the ability and willingness of private sector technology transfer partners to commercialize new technologies. For potential preventive, diagnostic, and therapeutic products, that willingness almost invariably hinges on the existence of patent protection in the United States and foreign countries for the technology in question.

The United States Patent and Trademark Office (PTO) and courts with jurisdiction over patent matters are the only entities that can make a definitive determination in the United States of the patentability of biomedical research discoveries, including human genetic material. Foreign countries similarly determine the scope and subject matter of patent protection within their boundaries. These determinations require a careful analysis of the particular facts and circumstances of each patent application.

Whether or not to file for patent protection on a given technology is a policy decision made at the discretion of the agency in which a Federal employee inventor works. Accordingly, the PHS has established the following policy to guide its agencies in the pursuit and maintenance of U.S. and foreign patent protection for PHS-owned biomedical technology.

C. POLICY

- The PHS will seek patent protection on biomedical technologies only when a patent facilitates availability of the technology to the public for preventive, diagnostic, therapeutic, or research use, or other commercial use. Generally, a patent is necessary to facilitate and attract investment by commercial partners for further research and commercial development of the technology, such as where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, a patent also might be necessary to encourage a commercial partner to make available for research use important materials or products.
- Patent protection generally will not be sought by the PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS generally will not seek patent protection for commercially valuable research tools (knock-out mice, receptors, cell lines) for the sole purpose of excluding others from using the patentable subject matter without a license. Such materials can be licensed under biological materials licenses or distributed to the research community without further compensation.
- PHS generally will not seek patent protection on a technology unless the commercial or public health value of the technology warrants the expenditure of funds for patenting. If PHS determines that a technology is patentable, but declines to seek patent protection due to low public health or commercial priority, waiver of patent rights to the employee-inventor of the technology may be appropriate and may be considered in accordance with applicable policies and procedures.
- When commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be commercialized through non-patent licensing, and some technologies are transferred to the private sector most expeditiously through publication. For those best transferred through publication, patenting and licensing are unnecessary and could inhibit broad dissemination and

application of the technology. Methods of performing surgical procedures, for example, could fall within this category.

- With regard to the patenting of research results arising under a Cooperative Research and Development Agreement (CRADA), PHS will evaluate whether to file for patent protection in accordance with these principles, to the extent consistent with the terms of the CRADA and the collaborative relationship.
- In accordance with a longstanding tradition of scientific freedom, PHS research results are published freely. Publication of research is not to be significantly delayed for the purpose of either filing patent applications on patentable subject matter, or conducting further research to develop patentable subject matter.
- With regard to the patenting of research results which are in early stages of development, PHS will file for patent protection only on research that has a practical utility or a reasonable expectation of future practical utility. Practical utility for this purpose is based on the reasonable expectation of at least one commercial or public health use that is directly and specifically related to the research results in question. For example, the practical utility of a cDNA sequence is determined according to whether a potential use is directly a consequence of the particular sequence, not a use common to all DNA.
- Once initiated, prosecution of patent applications and maintenance of issued patents will continue only as long as there exists a reasonable expectation of transferring the patent rights to a commercial partner through licensing.
- PHS will enforce and defend its patents, where appropriate, either through its own resources, by granting its licensees the right of enforcement and defense as provided by 35 U.S.C. 207 (a)(2), or by referring the matter directly to the Department of Justice. In any case, no litigation may be undertaken in the Federal Court system without approval of the Department of Justice.

E. EFFECTIVE DATE

The policies and procedures set forth in this Manual Chapter are effective immediately.

F. ADDITIONAL INFORMATION

Questions about this Manual Chapter may be directed to Ms. Barbara McGarey, Deputy Director, Office of Technology Transfer, on (301) 496-7057.

**United States Public Health Service
Technology Transfer Manual
Chapter No. 300**

PHS Licensing Policy

A. PURPOSE

This Manual Chapter sets forth the policy for licensing technologies developed in Public Health Service (PHS) laboratories.

B. BACKGROUND

The primary mission of PHS research laboratories is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner. PHS is cognizant of its role in protecting the public interest as NIH, FDA, and CDC technologies are transferred.

Realization of the considerable anticipated health benefits inherent in PHS conducted and supported biomedical research will depend in large part on the ability and willingness of private sector technology transfer partners to commercialize new technologies. For potential preventive, diagnostic, and therapeutic products, that willingness almost invariably hinges on the existence of patent protection in the United States and foreign countries for the technology in question.

C. POLICY

PHS generally seeks to patent and license biomedical technologies when a patent will facilitate and attract investment by commercial partners for further research and commercial development of the technology. This is critical where the utility of the patentable subject matter is as a potential preventive, diagnostic, or therapeutic product. However, it also could occur when a patent is necessary to encourage a commercial partner to keep important materials or products available for research use.

Patent protection generally is not sought by PHS where further research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic, or preventive uses are not reasonably anticipated. For example, PHS generally will not seek patent protection for research tools, such as transgenic mice, receptors, or cell lines. Such materials can be licensed effectively in the absence of patent protection, under royalty-bearing biological materials licenses, or distributed to the research community through nonroyalty-bearing material transfer agreements. For research tools, the public interest is served primarily by ensuring that the tool is widely available to both academic and commercial scientists to advance further scientific discovery. Secondly, a financial return to the public is obtained through royalties on the rare research tool that has significant commercial value.

In addition, when commercialization and technology transfer can best be accomplished without patent protection, such protection will not be sought. For example, some technologies may be transferred to the private sector most expeditiously through publication. For such technologies, patenting and licensing are unnecessary and could inhibit broad dissemination and application of the technology. Methods of performing surgical procedures, for example, could fall within this category.

In contrast, for technologies with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners. Due to the importance of effective patent licensing to the development and availability of new products arising from PHS technology, the PHS licensing program is governed by the following principles in marketing, negotiating, executing, and monitoring licenses to PHS patents:

- PHS seeks to ensure development of each technology for the broadest possible applications, optimizing the number of products developed from PHS technology. This is accomplished first and foremost through diligent assertion of inventorship (and thus ownership) rights to PHS technologies in accordance with current patent law. Second, PHS policy is to retain those ownership rights for transfer to the private sector through licensing instead of assignment. This strategy allows PHS to engage in licensing negotiations which ensure the broadest and most expeditious development of new products. Assignment of rights to the commercialization partner would inhibit the ability of PHS to have a meaningful role in monitoring and ensuring the development of the technology.

- PHS seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the technology. This ensures that as many companies as possible can obtain commercial development rights, resulting in the concurrent development of many potential applications. This is accomplished through:

--Negotiating non-exclusive or co-exclusive licenses whenever possible. This allows more than one company to develop products using a particular technology, products which may ultimately compete with each other in the marketplace. PHS recognizes that companies typically need an exclusive market position to offset the risk, time, and expense of developing biomedical diagnostic or therapeutic products, however, companies do not necessarily need to achieve that position by exclusively licensing a government technology used to develop that product. Instead, they frequently are able to add their own proprietary technologies to the technology licensed from the government to ultimately achieve some level of uniqueness and exclusivity for the final product.

--Negotiating and awarding exclusive licenses for specific indications or fields of use, based on the license applicant's commercial development ability at the time of application. This prevents one company from tying up license rights to applications that could be concurrently developed by another company.

--Negotiating provisions for mandatory sublicensing by exclusive licensees, particularly where a broad exclusive license is granted, as under a CRADA. CRADA exclusive licenses are granted to patents arising under the CRADA based on the scope of the CRADA research. The research, and therefore the patents, can be broad. Because CRADA partners obtain options to exclusive licenses at the onset of the CRADA, it is usually not appropriate to narrow the field of use to such licenses beyond the original scope of the CRADA research. Thus, PHS requires exclusive licensees to grant sublicenses to broaden the development possibilities when necessary for the public health.

--Negotiating requirements for continuing availability of the technology for further research. Although a technology has been licensed for commercial development, PHS seeks to maintain the availability of that technology for further research uses only by non-profit and for-profit entities. This advances science and stimulates further commercial development.

- PHS seeks to ensure that commercial partners expeditiously develop the licensed technology. This is accomplished through:

--granting license rights only to fields of use for which the company has submitted an acceptable commercial development plan to bring the technology to practical application. PHS typically does not grant license rights to venture capitalists, brokers, or other entities that are not in a position to develop the technology directly.

--negotiating specific commercial development milestones and benchmarks with proposed licensees so that development can be assessed and monitored;

--negotiating license execution fees, minimum annual royalty payments, milestone payments, and reimbursement of patent expenses in addition to earned royalty payments. Requiring a company to pay royalties "out of pocket" to acquire and keep the technology ensures that a company is committed to developing the technology and has not licensed the technology merely for competitive advantage.

- PHS seeks to ensure that technologies commercialized under PHS licenses are brought to practical application, offered and maintained for sale, and made reasonably accessible to the public. PHS enhances public access to the benefits of its technology by fostering the development of competing products for the same or similar applications. For example, PHS currently has several CRADAs and licenses which combine the significant expertise of its scientists with the knowledge and resources of different private partners for the development of two types of therapy (gene therapy and recombinant enzyme replacement therapy) for an inherited disease. The only therapy currently on the market to treat this disease is an expensive enzyme replacement regimen derived from placental tissue.
- PHS seeks to obtain a fair financial return on the public's research investment through negotiating royalty-bearing licenses and obtaining payment of patent expenses from licensees.
- PHS seeks to negotiate and obtain public benefits from licensees that are appropriate and consistent with expeditious commercial development and accessibility of the technology.
- PHS monitors the performance of PHS licensees and ensures that its licensed technology is fully developed, through the modification or termination of a license in the event that a licensee is unable to fully develop the rights granted. Modifying an exclusive license to a non-exclusive one, or narrowing the fields of use, allows PHS to license the technology to other companies for further development and sale. This is accomplished through:

--Negotiating specific grounds for modification or termination of the license. The PHS model exclusive license specifies nine grounds, including failure to meet commercialization benchmarks, failure to keep the licensed technology reasonably accessible to the public, and failure to reasonably meet unmet health care needs.

--Monitoring the commercial development activities of the licensees to determine compliance with the terms of the license agreement.

--Initiating administrative action to modify or terminate license rights where necessary.

E. EFFECTIVE DATE

The policies and procedures set forth in this Manual Chapter are effective immediately.

F. ADDITIONAL INFORMATION

Questions about this Manual Chapter may be directed to Ms. Barbara McGarey, Deputy Director, Office of Technology Transfer, on (301) 496-7057.

NIH Technology Transfer Mission Statement

The Department of Health and Human Services (DHHS) has designated the National Institutes of Health (NIH) as the lead agency for technology transfer for the Public Health Service (PHS). Within the NIH, the Office of Technology Transfer (OTT) has primary responsibility for technology transfer. This Office evaluates, protects, monitors, and manages the NIH invention portfolio to carry out the mandates of the Federal Technology Transfer Act of 1986. This is largely accomplished through overseeing patent prosecution, negotiating and monitoring licensing agreements, and providing oversight and central policy review of Cooperative Research and Development Agreements. OTT also manages the patent and licensing activities for the Food and Drug Administration (FDA). OTT is responsible for the central development and implementation of technology transfer policies for three research components of the PHS—NIH, FDA, and the Centers for Disease Control and Prevention.

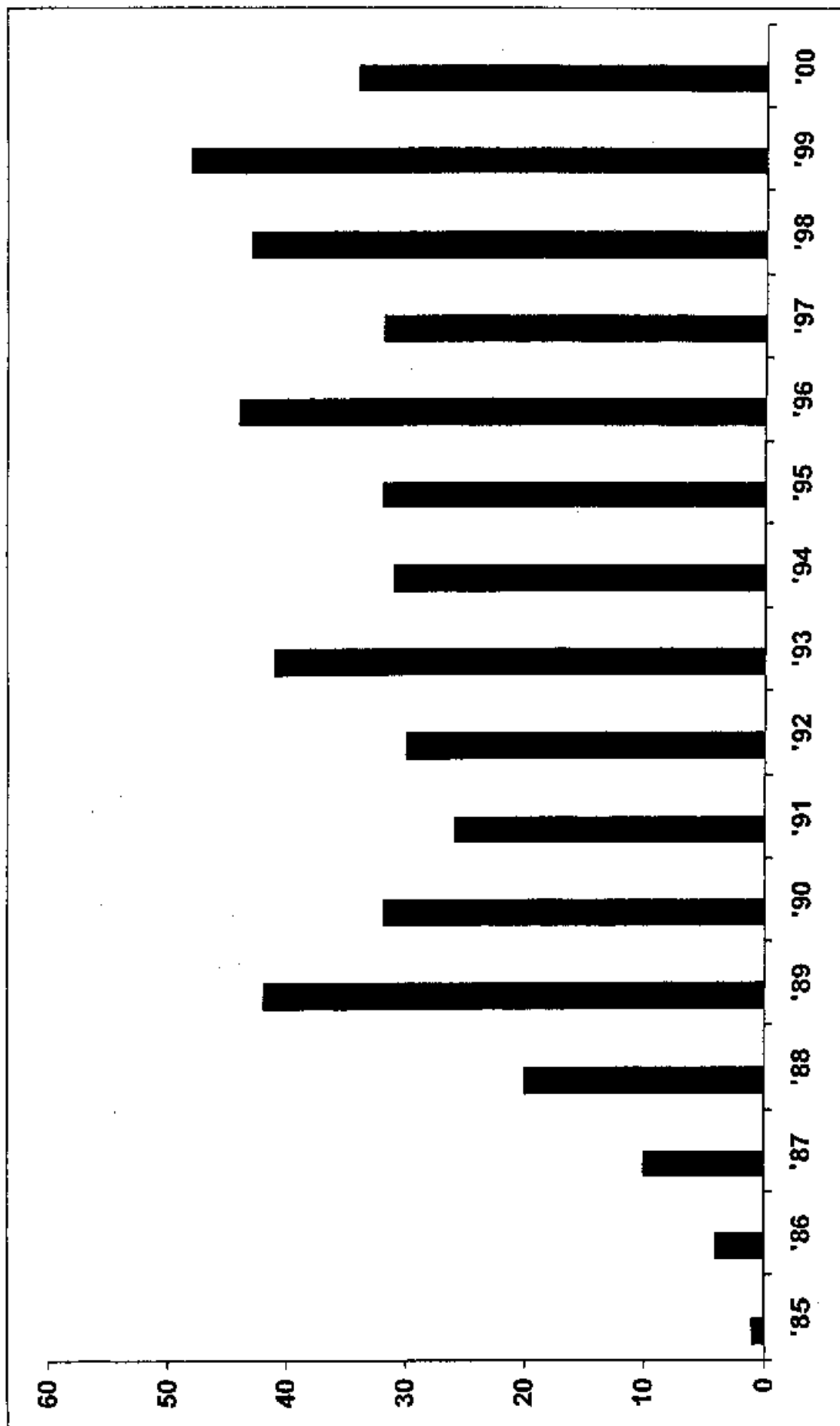
To the extent that current law permits, NIH has made deliberate efforts to return benefit to the taxpayers who support its research. NIH has developed and implemented a number of licensing strategies that balance new product development with appropriate market competition:

1. NIH negotiates non-exclusive or co-exclusive licenses whenever possible, so that more than one company can develop products in competition with one another. In FY 2000, 84 percent of all commercial development licenses executed by the NIH were non-exclusive; these represent the majority of diagnostic and research tool technologies in the NIH portfolio. The remaining 16 percent that were exclusive represent a majority of the therapeutic and vaccine technologies in the NIH portfolio.
2. NIH negotiates exclusive licenses for specific indications or fields of use, based on the license applicant's commercial development ability at the time of application. This prevents one company from tying up license rights to applications that could be concurrently developed by another company.
3. NIH negotiates requirements for continuing availability of the technology for further research. In this way, technologies that are licensed remain accessible to research personnel to advance science and stimulate further commercial development.
4. All NIH licenses can be terminated for failure to comply with the terms of the license, and NIH negotiates specific commercial development milestones and benchmarks with licensees so that development can be assessed and monitored.

5. NIH does not seek patent protection on a technology for which further research and development is not necessary to realize the technology's primary use. The NIH will seek patent protection for therapeutic, diagnostic or preventive uses and when a technology requires further research and development to bring a technology to practical application.
6. Where a broad exclusive license is granted, NIH negotiates provisions for mandatory sublicensing by exclusive licensees to broaden the development possibilities when necessary for the public health. Some exclusive licenses emanate from Cooperative Research and Development Agreements (CRADA). By law, CRADA partners can obtain an exclusive license to technology developed under a CRADA.
7. NIH includes public benefit provisions in its license agreement, when appropriate, such as a requirement that the drug developer provide a specified amount of the product, if one is commercialized, to indigent populations, or that the company establish a website to provide information on the disease for which the drug is being developed.

Appendix 4

NIH Executed Standard CRADAs



Appendix 5

List of Groups Consulted

The Council on Governmental Relations (COGR) - an association that develops policies and practices for administering federally sponsored research and training in universities.

The Association of University Technology Managers (AUTM) - an organization representing the technology managers and business executives in universities, research institutions, teaching hospitals, companies and federal agencies.

The Pharmaceutical Research and Manufacturers of America (PhRMA) - an organization that represents the country's leading research-based pharmaceutical and biotechnology companies.

Biotechnology Industry Organization (BIO) - an organization that represents the biotechnology industry.

The Association of American Medical Colleges (AAMC) - a non-profit association founded to work for reform in medical education. The Association now comprises medical schools, academic and professional societies, and the nation's medical students and residents.

The Association of American Universities (AAU) - an organization founded to advance the international standing of U.S. research universities, and representing sixty-three North American public and private universities.

Appendix 6

Interagency Edison: A Common Electronic Way to Meet Statutory Reporting Requirements Across The Government

A Business Case for the Edison System

Passage of the Bayh-Dole Act in 1980 resulted in statutory regulations that mandate reporting by award recipients of all inventions and patents derived through federal funding agreements: grants, cooperative agreements, and contracts. Every year, NIH-sponsored research yields thousands of inventions, such as biological agents, new drugs, laboratory equipment, and scientific processes. Some grantee/contractor organizations may have a single invention to report in a year, while others, such as large research universities, may have several hundred each year. The need to accurately receive and track reports for such subject inventions was emphasized in a Congressional inquiry held in August, 1994. Observations by Congress were followed by a report from the Office of Inspector General, DHHS issued that year, entitled, "NIH Oversight of Extramural Research Inventions." The report recommended a timely and decisive move to redefine the level of responsibility on the part of NIH for overseeing grantee/contractor compliance with Federal regulations concerning invention reporting and utilization. In response to the Inspector General's recommendations, the NIH Office of Policy for Extramural Research Administration moved to provide grantee/contractor organizations with a more accessible and efficient mechanism for submitting and tracking information about inventions and patents derived from NIH support.

The mechanism chosen to meet this need was unveiled in 1995 as "Edison", an interactive Web site for reporting, monitoring, and tracking inventions derived from federally-funded research. Specifically, Edison is a relational database system from which either representatives of extramural grantee/contractor organizations or federal agency staff can create, access, and modify records in a common file. Submission and monitoring of information in the Edison system permits grantee/contractor organizations to comply electronically with mandated invention reporting requirements.

Edison System Technology and Adoption by the Extramural Community

When introduced, Edison was one of the first innovative government systems to use interactive web technology to support the exchange of confidential information. Its use of the Internet as a platform avoided compatibility obstacles inherent in proprietary software design, and also provided accessibility for diverse populations of grantee/contractor institutions that include start-up companies with single users via public Internet providers as well as research institutions and for-profit corporate contractors.

As a system responsible for the submission and tracking of invention and patent information, confidentiality was a critical element in Edison's design. Institutions are required to register, and individual user accounts provide for authenticated sessions. Use of either of the most

popular Internet browsers, Netscape Navigator™ or Microsoft Internet Explorer™, ensures that information being transmitted remains confidential by the use of encryption technology. Unauthorized access to secondary screens in the Edison system is prevented by session-specific transient internal passwords that are completely transparent to the user.

From its introduction, grantee/contractor organizations have increasingly opted to use the Edison system. By the beginning of 2001, nearly 300 institutions have registered to use Edison. Given the fact that only a fraction of the approximately 2,000 grantee/contractor institutions ever develop inventive technologies from their research, projections suggest that the institutions now using Edison constitute more than 90 percent of prospective routine users.

Interagency Edison – A Government-Wide Invention Reporting System

Statutory regulations require the reporting of inventions derived through funding agreements with any federal agency. The desire to achieve a uniform reporting system throughout government suggested the use of the Edison system as a common gateway whereby grantee/contractors could submit reports to any agency through a single site.

In 1997, this vision was first realized through the addition of the National Science Foundation (NSF) to the Edison system. A separate database was established and, by simply identifying either NIH or NSF as the source of funding for inventive technologies, all reported information was routed into the appropriate database. With this expansion, the system renamed "Interagency Edison", and a high level Internet domain name, <http://iedison.gov>, was granted by the General Services Administration. This single gateway concept has been well received by the NIH and NSF grantee/contractor community as has now been adopted by 14 federal agencies whose grantees/contractors develop inventive technologies. NIH continues to support maintenance and operations of the overall system without charge to the other agencies.

Interagency Edison has now become the model for a similar distributed computing approach that is being pursued for electronic grants administration across the federal government in the "Federal Commons" initiative. The unqualified success of the Interagency Edison system has been demonstrated through its enthusiastic support by grantee/contractors and federal agencies. Use of the system has been estimated to reduce as many as 15 cycles of paper correspondence to an almost completely electronic business process, while setting a standard for meeting government-wide requirements through a single site. In recognition of meeting these objectives, the Edison system was recognized as a semi-finalist for the National Information Infrastructure Awards in 1996, and the design team received a prestigious Golden Hammer Award from Vice President Gore's National Performance Review in 1997.

Appendix 7

LIST OF THERAPEUTIC DRUGS

#	NAME	US SALES	CHEMICAL	COMPANY	USE	APP. DATE
1	PRILOSEC	4,183,490	Omeprazole	AstraZeneca Plc.	Ulcers	02/14/88
2	LIPITOR	2,997,636	Atorvastatin calcium	Warner Lambert & Pfizer Inc.	Hypercholesterolemia	12/17/96
3	PROZAC	2,567,168	Fluoxetine hydrochloride	Eli Lilly & Co.	Depression	12/29/87
4	PREVACID	2,360,649	Lansoprazole	Tap Holdings Inc.	Ulcers	05/10/95
5	ZOCOR	2,298,527	Simvastatin	Merck & Co.	Hypercholesterolemia	12/23/91
6	EPOGEN	1,834,434	Epoetin alfa	Amgen Inc.	Anemia	06/01/89
7	ZOLOFT	1,735,380	Sertalle hydrochloride	Pfizer Inc.	Depression	12/30/91
8	CLARITIN	1,531,361	Loratadine	Schering-Plough Corp.	Allergic rhinitis	04/12/93
9	PAXIL	1,512,677	Paroxetine hydrochloride	SmithKline Beecham Plc.	Depression	12/29/92
10	ZYPREXA	1,491,700	Olanzapine	Eli Lilly & Co.	Schizophrenia	09/30/96
11	NORVASC	1,480,924	Amlodipine besylate	Pfizer Inc.	Hypertension	07/31/92
12	CELEBREX	1,416,229	Celecoxib	Pharmacia Corp. & Pfizer Inc.	Osteoarthritis & rheumatoid arthritis	12/31/98
13	GLUCOPHAGE	1,316,193	Metformin hydrochloride	Bristol-Myers Squibb Co.	Type 2 diabetes	12/29/94
14	PROCRIT	1,260,499	Epoetin alfa	Johnson & Johnson	Anemia	12/31/90
15	PRAVACHOL	1,179,812	Pravastatin sodium	Bristol-Myers Squibb Co.	Hypercholesterolemia	10/31/91
16	AUGMENTIN	1,162,217	Amoxicillin & clavulante potassium	SmithKline Beecham Plc.	Bacterial infections	08/06/84
17	PREMARIN	1,080,221	Conjugated estrogens	American Home Products Corp.	Vasomotor symptoms associated with menopause	1942
18	RISPERDAL	1,034,431	Risperidone	Johnson & Johnson	Schizophrenia	12/29/93
19	NEUPOGEN (SORBITOL)	991,462	Filgrastim	Amgen Inc.	Neutropenia	02/21/91
20	IMITREX	946,531	Sumatriptan succinate	Glaxo Wellcome Plc.	Migraine	12/28/92
21	CIPRO	920,261	Ciprofloxacin hydrochloride	Bayer AG	Bacterial infections	10/22/87
22	VASOTEC	852,012	Enalapril maleate	Merck & Co.	Hypertension	12/24/85
23	NEURONTIN	851,361	Gabapentin	Warner-Lambert Co.	Epilepsy	12/29/93
24	TAXOL SEMI-SYN	846,487	Paclitaxel	Bristol-Myers Squibb Co.	Ovarian cancer & AIDS-related Kaposi's sarcoma	12/29/92
25	REZULIN	772,723	Troglitazone	Warner-Lambert Co. & Sankyo Parke Davis	Type 2 diabetes	01/29/97
26	DEPAKOTE	746,796	Divalproex sodium	Abbott Laboratories	Bipolar disorder, seizures, & migraine	03/10/83
27	CARDIZEM CD	732,396	Diltiazem hydrochloride	Aventis SA	Angina	11/05/82
28	ZESTRIL	724,059	Lisinopril	AstraZeneca Plc.	Hypertension	12/30/87
29	PEPCID	719,949	Famotidine	Merck & Co.	Ulcers	10/15/86
30	ZITHROMAX Z-PAK	712,605	Azithromycin	Pfizer Inc.	Bacterial infections	11/04/91
31	BIAXIN	693,578	Clarithromycin	Abbott Laboratories	Bacterial infections	10/31/91
32	FOSAMAX	671,466	Alendronate sodium	Merck & Co.	Osteoporosis	12/29/95
33	VIAGRA	666,695	Sildenafil citrate	Pfizer Inc.	Erectile dysfunction	03/27/98
34	PROCARDIA	626,492	Nifedipine	Pfizer Inc.	Hypertension & angina	09/06/89
35	AMBIEN	613,503	Zolpidem tartrate	Searle	Chronic insomnia	12/16/92
36	PREMPRO	610,189	Conjugated estrogens	American Home Products Corp.	Vasomotor symptoms associated with menopause	1942
37	OXYCONTIN	602,605	Oxycodone hydrochloride	Purdue Pharma LP	Pain reliever	12/12/95
38	BUSPAR	591,899	Buspirone hydrochloride	Bristol-Myers Squibb Co.	Anxiety disorders	09/29/96
39	WELLBUTRIN	583,343	Bupropion hydrochloride	Glaxo Wellcome Plc.	Depression	10/04/96
40	ZYRTEC	580,245	Cetirizine hydrochloride	Pfizer Inc.	Allergic rhinitis & chronic idiopathic urticaria	12/08/95
41	PROPULSID	558,172	Cisapride	Johnson & Johnson	Gastroesophageal reflux disease	07/29/93
42	ROCEPHIN	556,707	Sterile ceftriaxone sodium	F. Hoffman-La Roche Ltd.	Bacterial infections	12/21/84
43	ALLEGRA	553,099	Fexofenadine hydrochloride	Aventis SA	Allergic rhinitis	07/25/96
44	REBETRON	547,799	Ribavirin & interferon alfa-2b, recombinant	Schering-Plough Corp.	Hepatitis C	07/03/98
45	HYTRIN	540,693	Terazosin hydrochloride	Abbott Laboratories	Benign prostatic hypertrophy and hypertension	08/07/87
46	LEVAQUIN	533,554	Levofloxacin	Johnson RW	Bacterial infections	12/20/96
47	ZOFRAN	532,752	Ondansetron hydrochloride	Glaxo Wellcome Plc.	Nausea and vomiting	01/04/91

Appendix 8



Congressional Directive to NIH for "Return on Investment"

The conference report to appropriations legislation funding the National Institutes of Health and other agencies in FY 2001 contained the following language:

The conferees have been made aware of the public interest in securing an appropriate return on the NIH investment in basic research. The conferees are also aware of the mounting concern over the cost to patients of therapeutic drugs. By July 2001, based on a list of such therapeutic drugs which are FDA approved, have reached \$500,000,000 per year in sales in the United States, and have received NIH funding, NIH will prepare a plan to ensure that taxpayers' interests are protected.¹

This language reflects a compromise to an amendment introduced by Sen. Ron Wyden (D-Oregon) on June 23, 2000² and proposals by Sen. Paul Wellstone (D-Minn.) and Rep. Bernie Sanders (I-Vermont) relating to "reasonable pricing" of pharmaceuticals. NIH is expected to complete its directive in July.

According to the NIH Office of Technology Transfer, 47 FDA-approved therapeutic drugs under patent currently generate U.S. sales of more than \$500 million annually. In discussions with Congress, the NIH has agreed to draft a plan that focuses on the "return on investment" of public funding supporting drug development.

NIH-funded research has generated thousands of patents held by universities and other institutions.³ Only one of the 47 FDA-approved drugs identified as generating \$500 million or more in sales has been determined by NIH to be derived directly from a patent generated by NIH-funded research. Although several more "blockbuster" drugs from patents issued on NIH-sponsored research may soon become available, the agency is currently developing its plan on the basis of the single major-selling drug developed from a university-held patent. The specifics of the NIH plan under development are as yet uncertain.

Background: Sen. Wyden's original amendment proposed to require, "as a condition of receiving a grant or contract from the National Institutes of Health," assurance from an academic institution or other entity to transfer to the NIH director a percentage of funds made available from licenses or sales of a broad range of pharmaceuticals. Assumedly,

¹ Report 106-1033, Conference Report to accompany H.R. 4577, Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 2001. December 15, 2000.

² See Appendix I, attached.

³ See NIH Office of Technology Transfer and "Edison" database, <http://www.iedison.gov/>.

the requirement was presented as a "pay-back" for the original NIH research grant or contract awards. The threshold of \$500 million in annual sales applied to "any pharmaceutical, pharmaceutical compound or drug delivery mechanism (including biologics and vaccines) approved by the Food and Drug Administration" resulting from an award.

The Conference Report language is the latest in a series of Congressional actions touching on concerns about the price of pharmaceuticals derived in part from publicly funded research. An earlier initiative, the reasonable pricing clause, focused directly upon industry partnerships under NIH Cooperative Research and Development Agreements (CRADAs). In the 1990s, expressions of interest from industry in NIH CRADAs plunged following introduction of the reasonable pricing clause, and the clause was subsequently rescinded.

The sentiments reflected in the conference report were articulated by the new chair of the subcommittee overseeing NIH appropriations:

The Senate Labor/HHS appropriations subcommittee [May 23, 2001] held a hearing on the NIH budget. During the session, ranking member (and soon to be chairman) Tom Harkin (D-IA) asked about the support NIH had provided for research on a new anti-leukemia drug, Gleevec, which the Food and Drug Administration approved two weeks ago. National Cancer Institute director Rick Klausner responded that NIH had made grants totaling \$4 million for specific work on the drug, and that much of the underlying research--which went back decades--had also been supported by NIH. Harkin responded that the cost of this drug to consumers was \$2,000 to \$3,000 a month, and said he "wondered about the pricing, and about re-capturing some of the costs." "We need to figure this one out, how to get some of the money to come back to NIH," he said. "This is an issue that will be coming down the road."⁴

Analysis: The conference language contravenes several prevailing and critical aspects of federal science and technology policy, including the Bayh-Dole Act and related legislation. To promote the dissemination of useful knowledge, federal policy has generally sought to encourage academic institutions receiving federal research awards to transfer technology arising from this research to the private sector through licensing arrangements or other agreements.

The vast majority of the NIH's extramural research is performed by academic institutions (more than \$12 billion in FY 2001) and published and broadly disseminated without monetary returns to the institutions or to NIH. However, federal statutes (the Bayh-Dole, Stevenson-Wydler, and other Acts) and policies direct academic and other non-profit awarded institutions, where advisable, to seek patents on inventions arising from federally sponsored research in order to catalyze commercial development.

⁴ Reported by the American Association of Universities, AAU CFR Update 01-#96, May 24, 2001.

The origin of the Bayh-Dole Act (P.L. 96-517) arose from concerns of the 1960s and 1970s that many potential research products were "lying fallow" in academic institutions because of a lack of sufficient incentive for commercializing research inventions. Moreover, the Federal policies on patenting and licensing of sponsored research at that time relied greatly on non-exclusive licensing and other conditions that further discouraged partnerships with private sector firms. In order to encourage more efficient transfer of technology from federal research grants to broad public or commercial application, the Bayh-Dole Act of 1980 permits academic institutions to retain rights and title to inventions produced under federally sponsored research without seeking prior approval from federal agencies. With passage of the Bayh-Dole Act, patents issued to universities and other non-profit institutions have risen from fewer than 250 in 1980 to more than 2000 annually.⁵ Many of the patents generated with federal support are attributable to NIH research.

Many commentators attribute the Bayh-Dole Act's remarkable success to its explicit promulgation of incentives for academic and other non-profit institutions to pursue commercial licensing of inventions arising from research. In fact, such incentives had existed prior to passage of the act. The significance of Bayh-Dole was that it required federal research awardees to pursue the application of their research into products and practice, and it removed the federal government as a party to negotiations. The act thereby encouraged commercial entities and venture capitalists to negotiate licensing arrangements with academic institutions without fear of federal intercession.⁶

The Bayh-Dole Act's key objective, as stated in its preamble (35 USC § 200), is to encourage dissemination and utilization of technology. The act does not seek to promote a commercial return to federal agencies or academic institutions on research investment.

In fact, while the number of patents issued to universities and other non-profit institutions has increased dramatically since passage of the act, the great majority of these patents do not generate significant revenues or even sufficient revenues to compensate the patenting expenses.⁷ The information contained in these patents nevertheless remains publicly available within the records of the U.S. Patent and Trademark Office. The conference report language, by focusing on the rare (<1:1000) sub-class of university-owned patents that are commercially successful, does not take into consideration the great number of patents obtained by universities at their own risk and expense that never succeed commercially. Further, the act requires institutions to reinvest licensing income back into research, which the institutions do. The conference language's direction to NIH runs contrary to the express intentions of Bayh-Dole and would represent a major departure from prevailing federal policy.

⁵ AUTM survey.

⁶ Testimony of Howard Bremer, Ph.D., October 25, 1993. From Council on Governmental Relations, Washington DC.

⁷ See, for the example of one major research institution, Katherine Ku, Effect of Patenting and Technology Transfer on Commercialization, presentation to the National Academies, April 17, 2001. Available at: <http://www.nationalacademies.org/lp>, accessed June 8, 2001.

There is currently a substantial return on investment from NIH and other federally funded biomedical and scientific research.

The fundamental rationale of federal science policy since the end of World War II has been to invest tax dollars in basic research to promote the societal returns of improved health, strengthened national security, and enhanced economic performance. This has been the central argument advanced in the Congress for funding NIH and other science agencies, and has been echoed by the advocacy community:

Federal support for basic science is an aspect of spending that has a payback, and a massive one at that. It puts money out and gets back new products, healthier people and cash...significantly increasing our federal investment in basic medical and scientific research will pay handsome dividends in the 21st Century.⁸

In the 1950s, economist Robert Solow demonstrated that more than half of the U.S. annual growth in GNP was attributable to new technologies and new knowledge, as opposed to increases in land, labor, or other "traditional" capital inputs.⁹ Solow, a Nobel laureate and MIT faculty member, believed that university-based research along with industry R&D was a substantial component of this growth. The relationship of academic research with industrial innovation and prosperity was further established by Edwin Mansfield,¹⁰ Nathan Rosenberg and Richard Nelson¹¹, and numerous other leading economists. Joseph Stiglitz, serving on the President's Council of Economic Advisors, reported estimates of a social rate of return on federally funded research between 25% and 50% annually. He summarized his views to the National Science Board: "Advances in knowledge are essential to spurring economic growth. There are only a few things that economists really agree upon, and this is one of them."¹²

Improvements to health from medical and other research have been documented in numerous ways. Many of these have focused on case studies of the role of (primarily basic) academic research leading to development of specific products or therapies^{13,14}. In studies of health outcomes, the demographer Kenneth Manton and colleagues have measured declining rates of disability and generally improved quality of life indicators among older Americans, which directly correlate with innovations from biomedical research.¹⁵ Improved levels of day-to-day functioning of older Americans have welcome

⁸ Peter Lynch, financial analyst, quoted in *Exceptional Returns: the Economic Value of America's Investment in Medical Research*. Funding First, Washington, DC, May 2000.

⁹ Solow has produced numerous reviews of this "growth accounting" research, including, *Technical change, capital formation and economic growth*. *American Economic Review*, 1962; 52:76-86.

¹⁰ Mansfield E. Academic research and industrial innovation. *Research Policy* 1991; 1-12.

¹¹ Rosenberg N, Nelson RR. American universities and technical advance in industry. *Research Policy* 1994; 23: 323-348.

¹² Transcript of National Science Board meeting, open session, March 23, 1995.

¹³ Connor JH, Dripps RD. The top ten clinical advances in cardiovascular-pulmonary medicine and surgery. Final report, January 31, 1977. NIH NHLBI contract 1-HO-1-2327.

¹⁴ Dustin HP, Rocella EJ, Garrison HG. Controlling hypertension: a research success story. *Archives of Internal Medicine*, 1996;156:1926-35.

¹⁵ Manton KG, Corder KS, Stallard B. Monitoring changes in the health of the U.S. elderly population: correlates with biomedical research and clinical innovations. *FASEB Journal*, 1997; 11:923-930.

implications for the financial burden of care placed on families and federal programs, such as Medicare.¹⁶ These studies do not purport to measure speculative "cost savings" from specific innovations in medical care resulting from medical research; they do demonstrate significant improvements in health care correlated with biomedical research.

Americans widely recognize the generative effects of academic research on the electronic and computer science industries, as seen in Silicon Valley, Boston's I-128 corridor, and North Carolina's Research Triangle. Similarly, federal investments in biomedical research, which led directly to the development of the biotechnology industry, are reflected in the geographic concentration of biotechnology firms near leading biomedical research centers in the San Francisco Bay area, Southern California, New England, Maryland, and elsewhere. The growth of high technology industries near universities and research centers is the result of interactions with leading academic scientists, ideas, and pools of university trained personnel.¹⁷ Comparatively little, if any, of the commercial value of these enterprises remunerates universities directly. Rather, these industries provide a foundation for job creation, economic growth, and improved quality-of-life that are highly prized by state and local governments and their Congressional delegations.

The annual survey of the Association of University Technology Managers (AUTM) reports that licensing by member academic institutions (including major teaching hospitals) "contributed over \$40 billion in economic activity and supported more than 270,000 jobs in fiscal year 1999."¹⁸ *They estimate this activity to have generated \$5 billion in U.S. tax revenues for federal, state, and local government.* More than 60% of licenses and option agreements by AUTM members were made to small businesses, which are leading sources of job growth and economic development.

Summary: the AAMC objects to the conference report language on the grounds that it proposes to tax a rare source of unrestricted university revenues. These revenues are reinvested in basic research and training to help pay for the infrastructure necessary to be a competitive research institution, and to help support the significant cost-sharing that federal research funding presently obligates.¹⁹

The conference report's language is unwise policy. American taxpayers currently receive an extraordinary return on their investment in biomedical and other scientific research, through a system of governmental, academic, and industrial interaction that other nations are struggling to emulate. The historic success of these policies, together with new scientific opportunities and public health needs, are the basis of our advocacy for an expanded NIH budget and support of other federal science agencies.

¹⁶ *Ibid.*

¹⁷ For an analysis of the role of "star scientists" in biotechnology, see Zucker LG, Darby MR. The economists' case for biomedical research, in *The Future of Biomedical Research*. Washington, DC: American Enterprise Institute, 1997.

¹⁸ AUTM Licensing Survey: FY 1999, Survey Summary.

¹⁹ See also Appendix 2, editorial by Donald Kennedy in *Science*, June 8, 2001.

Recommendations:

- The AAMC, working closely with the university and research community, should reaffirm the nation's commitment to existing federal science policies, which yield substantial returns to society on public investment in research and development.
- The AAMC should oppose any proposal to redirect institutions' income in a manner other than that already required by the Bayh-Dole Act and current regulation.

Appendix 1: Original Wyden Amendment

WYDEN AMENDMENT NO. 3616 -- (Senate - June 23, 2000)

[Page: S5750]

(Ordered to lie on the table.)

Mr. WYDEN submitted an amendment intended to be proposed by him to the bill, H.R. 4577, *supra*; as follows:

On page 33, line 16, strike the period and insert the following: ``: Provided further, That the Director of the National Institutes of Health shall ensure, with respect to funds appropriated under this Act, that--

``(1) an entity that receives a grant or contract, made available with the appropriated funds by the National Institutes of Health, to conduct research shall provide the Director, at intervals of time determined appropriate by the Director, with information relating to--

``(A) any pharmaceutical, pharmaceutical compound or drug delivery mechanism (including biologics and vaccines) approved by the Food and Drug Administration that is manufactured from a technology that--

``(i) is developed, in whole or in part, using the results of such research; and

``(ii) has been licensed, sold or transferred by the grantee or contractor to an organization for manufacturing purposes;

``(B) the utilization of each such technology that has been licensed, sold or transferred to another entity;

``(C) the amount of royalties, other payments, or other forms of reimbursement collected by the grantee or contractor with respect to the license, sale or transfer of each such technology; and

``(D) the aggregate amount of the specific grants or contracts that were used in the development of such transferred technology.

``(2) an annual report is prepared and submitted to the appropriate committees of Congress that contains a summary of the information provided to the Director under paragraph (1) for the period for which the report is being prepared;

``(3)(A) as a condition of receiving a grant or contract from the National Institutes of Health to conduct research, an entity shall provide assurances to the Director that such entity will, as a part of any agreement that is entered into by the entity to license, sell, or

transfer any technology that is developed, in whole or in part, using the results of such research, require the repayment by the licensee, purchaser, or transferee (or the entity if the entity is using the technology in a manner described in this subparagraph) to the Director of an amount (determined under subparagraph (B)) of the funds made available through the grants or contracts as reported by the entity under paragraph (1)(D), if the licensee, purchaser, or transferee uses the technology to manufacture a pharmaceutical, pharmaceutical compound, or drug delivery mechanism (including biologics and vaccines) that is approved by the Food and Drug Administration;

“(B) the amount of the funds made available through the grant or contract to be repaid under subparagraph (A) shall be determined according to a fee schedule that--

“(i) is established by the Director; and

“(ii) shall ensure that--

“(I) the amount is based on a percentage of the net sales of the pharmaceutical, pharmaceutical compound, or drug delivery mechanism (including biologics and vaccines) that is referred to in subparagraph (A); and

“(II) the aggregate amount is limited to the aggregate amount of the funds made available through the grants or contracts involved; and

“(C) the amount described in subparagraph (B) shall be repaid to the Director, who shall deposit any such amount in an account and distribute funds from the account to the various offices of the National Institutes of Health for research conducted by the various offices, according to the scientific merit presented by the research projects involved; and

“(4)(A) with respect to an entity that is required to repay funds under paragraph (3), if the net sales of the pharmaceutical, pharmaceutical compound, or drug delivery mechanism (including biologics and vaccines) involved exceed \$500,000,000 (or the increased or decreased amount determined under subparagraph (B)) in any calendar year, the entity shall pay to the Director (as a return on the investment made by the Director through the grant or contract involved) for

[Page: S5751]

such year an amount equal to 1 percent of the amount by which such net sales exceed \$500,000,000 (or such increased or decreased amount) in such year; and

“(B) the \$500,000,000 amount referred to in subparagraph (A) shall be increased or decreased, for each calendar year that ends after December 31, 2000, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the Index for September of 2000.”

Appendix 2: Editorial from *Science*, June 8, 2001

Drug Prices: Real Problem, Wrong Solution

Donald Kennedy

Drug pricing has been an important political issue, off and on, ever since the Kefauver hearings in the late 1950s, and it now reappears in a strange disguise. After several failed efforts at passing "reasonable pricing" legislative amendments, Congress now will be asked to consider targeting--guess what?--not the drug companies, but U.S. research universities. Senator Ron Wyden (D-OR) has introduced language instructing the National Institutes of Health (NIH) to submit to Congress a plan whereby, if a drug produces half a billion dollars or more in sales and was developed from NIH-supported work in universities, the government should recover some of the profits. That would undercut a long-standing government policy that encourages technology transfer and has produced a rich harvest of innovation.

The concern is easy to understand: Drug pricing now threatens to block medical rescue for some of the world's most afflicted people. The African AIDS epidemic has awakened consciences across the developed world. Some of the promising but costly therapies were developed from basic research conducted at universities, which own patents on the discoveries and have been collecting royalties from commercial licensees. Angry students at Yale and Minnesota have been protesting those payments, and their anguish is understandable: To have workable but unaffordable therapies for this disease is difficult to accept. Thus, intense political scrutiny has been focused on the universities as well as the drug companies.

Just as hard legal cases can make bad law, emerging crises often make bad policies. Senator Wyden wants to attack the problem by reaching for the most available handle--the universities. His approach rests on persuasive-sounding logic: NIH has made substantial investments in basic research in universities; that research has led to successful drugs developed by pharmaceutical companies; and universities are receiving large royalty payments in return. All of this is true and reflects exactly what was intended by the Bayh-Dole Amendments in 1980. That legislation permitted universities to develop intellectual property protection for their inventions even when federal funding supported the work, thus encouraging the transfer of inventions to commercial developers. As university technology licensing offices become more sophisticated at negotiating terms with industry, royalty revenue streams have become large enough to attract political attention, although they contribute only trivially to a drug's price.

Does that mean that the government should get some of that revenue back? That's what Wyden thinks. Leaving NIH some room to be creative, he has offered two different recoupment proposals. One would have NIH receive some fraction of each royalty stream--in effect, garnishing the payments to the university. The other would require that

universities return the value of the grant that led to the product. The agency now must develop a response, due in July 2001, telling Congress what it proposes to do.

NIH and its congressional overseers should consider two problems. One is practical: The scientific and economic history of innovation tells us that its trajectory is tortuous and often obscure. To demonstrate that one particular grant gave rise to a discovery that in turn enabled the development of a specific drug will not be easy. The second is economic: Long before Bayh-Dole (indeed, back when Vannevar Bush presided over the conversion of military research into the plowshare of basic academic work), it was understood that the role of federal funding was to promote discoveries that would then attract the risk capital necessary for subsequent product development. The public would then benefit not only from the products themselves but also from the new employment and tax revenue they would generate.

Before Congress contemplates such a radical reformulation of Bayh-Dole, it should conduct a careful study of the present returns to the government from past basic research support. The guess here is that such an analysis will demonstrate that the economic benefits are very large indeed. If that is true, it would be a serious policy error to risk diminishing the incentives for technology transfer in order to divert some of the same income that helps support further university research. If the eggs really are golden, why punish the goose? As for the universities, they might think again about whether it's wise to press for continued royalty payments on real "blockbuster" drugs, especially those serving the most vulnerable populations. Sometimes it's politically wiser to let enough be enough.

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Appendix 9



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

June 11, 2001

Maria Freire, Ph.D.
Director
Science & Technology
Office of Intramural Research
National Institutes of Health
6011 Executive Blvd., Suite 325
Rockville, MD 20852-3804

Dear Dr. Freire:

Maria

Thank you for taking the time to meet with several representatives of Biotechnology Industry Organization (BIO) and its companies regarding the report to Congress on appropriate return on investment as requested in last year's Appropriations conference report. BIO believes that the National Institutes of Health and its Office of Technology Transfer have done a remarkable job of achieving their mission and providing the taxpayers the kind of return on investment they expect and deserve.

Dealing with government agencies can be frustrating, but we find that for all the requirements faced by the Office of Technology Transfer (OTT), you and your agency are extremely adept and competent in licensing technologies and negotiating CRADAs with our companies. While speeding up the process would provide incentives to our industry to do more, we recognize the larger public interest you must consider. OTT's serious and energetic approach to licensing has been successful in achieving its ultimate mission of improving public health.

This leads us directly to point one: NIH is a government agency, not a business. Its mission is to serve the broader public good, not conduct research for profit. The fact that you license technologies and negotiate CRADAs as an equal partner to industry is a tribute to your abilities, experience and commitment to protecting the public interest.

If monetary income is not the purpose of NIH and your office, then an appropriate return on investment needs to be measured in parameters other than dollars returned to NIH. First and foremost, the basic science performed and supported by NIH leads to greater scientific knowledge throughout the world. This, in turn, leads to additional research, both NIH-sponsored and private. This research yields lifesaving therapeutics and diagnostics -- an unequivocal appropriate return on investment.

Another clear return on investment is that the scientific training provided by the NIH leads to the development of the best scientists in the world. The United States is the

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cradle of scientific research. NIH scientists and scientists who have had the benefit of NIH funding for research play a part in driving the economy.

According to the 1999 Ernst and Young report, the biotech industry employed 162,000 people and paid nearly \$10 billion in taxes, including income, corporate and other federal, state and local taxes. This thriving segment of our modern economy provides a myriad of returns to the taxpayers for their generous and forward thinking investment in basic medical research.

The biotechnology industry continues to lose \$5.1 billion per year. Of nearly 1,500 companies, only 15 currently have profitable biologics on the market. We continue to be a high-risk long-term investment. NIH and university licensed research is still "early stage" research with no guarantee of success. As a result, companies can risk only limited investments in licensed science and technologies. If fees or royalty requirements increase, companies must demand greater returns, given the risk.

Some companies look to license research tools rather than technologies that could lead directly to FDA-approved prescription biologics. These tools can provide a method or a portion of the process for discovering or producing a therapy, but are not a part of the treatment itself. They are not guaranteed to be successful. Thus, many of NIH's licensable technologies cannot be expected to result in sizable monetary returns. NIH has established a policy that research tools should be made as widely available as possible so that as many researchers as possible can take advantage of the NIH investment. NIH has made the determination, consistent with its mission, that a public health benefit will be derived from wide distribution of its research tools.

Licensing fees for these tools, or for any technology, does provide NIH with a direct monetary return on its investment. The negotiations for these licensing agreements ensure an appropriate return because your office does not sign an agreement without appropriate licensing and royalty clauses. Likewise, if the licensing and royalty requirements were too harsh, companies would walk away from the deal. The fact that you are licensing technology and negotiating a substantial number of CRADAs shows you are able to balance a monetary return to NIH with the public need to transfer the technology for applied research in order to achieve the ultimate goal of improved treatments and public health.

Similarly, the public good is served through the licensing accomplished by universities. Bayh/Dole agreements have been very successful at transferring the NIH-supported research to the private sector for applied research. These agreements, like the CRADAs, are high-risk investments for private companies and often do not pan out. Several universities have done well with the royalties paid by companies that have had success. This has provided the incentive for greater activity in attempting to forge such agreements. Not only is the science developed further, which may lead to new products,

agreements. Not only is the science developed further, which may lead to new products, but a portion of the fees and royalties paid to universities gets turned back into additional research, giving a double "bang" for the appropriated "buck."

Companies paid \$390 million in royalties and \$725 million in license fees to U.S. universities on nearly 7,500 licenses/options in 1998 (according to AUTM FY 98 Survey Summary). The NIH received \$52 million in royalties in 1999. Our companies believe that these payments provide a rate of return to the government comparable to the rate of return on technology transferred between and among companies.

There is no standard "royalty" built into technology, Bayh/Dole or CRADA licenses. The science licensed is often at different stages. The earlier the stage the greater the risk to the company, and therefore the lower the royalty. No one can predict which idea will lead to a blockbuster drug. There is no clause stipulating that if the license leads to failure the private sector will receive a refund. This is the risk of the marketplace. In fact, of all CRADAs, only one has led to a product with greater than \$500 million in sales per year. This one drug had many unique factors in leading up to the CRADA and development, including some clinical trials done by NIH. Yet even here, there continued to be a risk of failure as the company pursued additional clinical trials.

For one drug to be approved by the FDA, a company typically needs to screen between 5,000 and 10,000 compounds. Of those, an average 250 lead to pre-clinical testing. Only about 5 of these make it to clinical testing, and with 80% passing Phase I, another 30% pass Phase II and then another 80% pass Phase III clinical testing. Each stage of research and development is high risk and has even higher costs. Even if companies could license potential compounds that had completed Phase II clinical trials, there would continue to be substantial risk of failure. Additionally, Phase III clinical trials are associated with the highest costs.

Negotiating licenses and royalties is a part of establishing a business relationship and negotiating a business transaction. The government should not establish pre-set royalty fees. If such fee schedules are established, and companies find them burdensome, it will only drive away companies from transferring the technology generated by NIH grants, thereby reducing the rate of return to the general public on the NIH research.

Establishing a royalty for a blockbuster drug is questionable, too, because "blockbuster" status is so rare. Should the percent go up or down? With university agreements it varies. Should a percentage be set aside for indigent care instead? Most universities and all companies with FDA-approved products already provide for this. Setting aside a portion of the blockbuster drug for this purpose could offset the "out-of-pocket" expenses already being set aside for indigent care.

Maria Freire, Ph.D.

June 11, 2001

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In summary, entities that obtain licenses to further develop technology initially supported by NIH currently pay licensing fees to initiate such research and often pay royalties on sales when and if the entities obtain FDA approval. Additional remuneration comes to the federal government via taxable income on sales of such products. More importantly, the public and taxpayers see the best return on investment through improved patient care obtained through advances in drug and biologic development. Long-term effects of breakthroughs in drug and biologic development also improve the quality of life and enable individuals to maintain participation in the labor force, thereby contributing to Federal and state tax revenues.

We understand why Congress has inquired about an appropriate return on investment in NIH. All taxpayers, individual and corporate, want to know that their tax dollars are being spent wisely and achieving the public good for which they were collected. In fact, this issue can be raised about all of the research and development done or supported by government, whether it be the airline industry, the high-tech internet or communications industries, or NASA and the aerospace industry.

Finally, we refer you to the May 2000 report from the Office of the Chairman of the Joint Economic Committee entitled, "The Benefits of Medical Research and the Role of NIH." The Executive Summary states, "Publicly funded research in general generates high rates of return to the economy, averaging 25 to 40 percent a year." This Congressional report clearly defines the purpose of NIH and its valuable return on investment. NIH needs to be evaluated as a whole, not just by the results of the OTT and not on any single division or department. In short, Congress has answered its own question; the taxpayer receives an appropriate return.

We believe that the investment in NIH and scientific research has achieved every goal Congress could have desired. Our industry has been spurred by that investment and we are proud to give back so much in potential public health outcomes as well as what we return to the economy in general.

Sincerely,



Carl B. Feldbaum

President

Biotechnology Industry Organization

CBF:mb1

Appendix 10

Alan F. Holmer
PRESIDENT AND CHIEF EXECUTIVE OFFICER



July 3, 2001

Maria Freire, Ph.D.
Director
Science & Technology
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804

Dear Dr. Freire:

The history of biomedical science in the Twentieth Century is one of remarkable accomplishments and advances in the treatment of many diseases and conditions. A major role in these developments has been the collaborations between NIH Intramural researchers and their colleagues in the innovative pharmaceutical companies of America. The Congress and Administrations of both political parties have consistently encouraged these collaborations. Virtually all policy makers in the past two decades have recognized the fundamental truth that the maximum benefit to the American people is the creation of increased scientific knowledge and its rapid dissemination through commercial products developed by the private sector.

We appreciate the singular contributions to the public health and welfare made by you and your colleagues at the Department of Health and Human Services and the National Institutes of Health. The partnership between our industry and the NIH has well served the interests of the American people.

Recently, some concern has been expressed about whether the Federal government is obtaining optimal benefits from technology transfer with respect to certain pharmaceutical products. This letter will attempt to respond to that concern by analyzing it in its discrete elements.

There are two different types of research undertaken using NIH funding; intramural and extramural. With respect to the research undertaken at the NIH by NIH researchers, the record is clear and unequivocal. The NIH leads the Federal government – and indeed the world – in the commercialization of its research

Pharmaceutical Research and Manufacturers of America

product. Your office has consistently negotiated with the private sector to advance the interests of patients. You have sought to secure licensing terms that are comparable to commercial arrangements when such arrangements are appropriate. You have also sought to advance both scientific knowledge and patient benefits when non-exclusive licenses are appropriate in platform technologies.

With respect to the extramural research funded by the NIH, that work is generally designed to advance the level of understanding of basic scientific questions. According to one major university system, these grants rarely produce patentable and licensable technologies. It is not common for these licenses to produce substantial royalty or other income. Thus, as tempting as it might appear to seek return of a portion of the NIH funds, such a proposal would likely be extremely difficult to implement and could ultimately cause significant harm to universities and their research programs.

Current practice of technology transfer between universities and the private sector has worked remarkably well. It has helped to create dramatic new industries in the life sciences including biotechnology, genomics, and bioinformatics. These technology transfers have played a central role in stimulating the growth of economic clusters in Silicon Valley, the Route 128 corridor, Houston, Texas, and Research Triangle Park, North Carolina. Imposing new hurdles to this kind of technology transfer will likely stifle those developments.

We respectfully suggest two measures that could increase the transparency of licensing arrangements. First, we suggest that the NIH provide some additional data in the annual report to the Congress and the public in order to outline the success you have had in securing positive results in technology transfer. Specifically, this report could detail the manner in which you negotiate and obtain licenses on commercially viable terms. In addition, the report could focus on the criteria you apply in determining when and whether to seek an exclusive or nonexclusive license. Finally, the report could provide a comprehensive assessment of the public health and socio-economic benefits of technology transfer.

Second, with respect to extramural research, we recognize that there is a need to have the grantees comply with the terms of the Bayh Dole Act of 1980 and to utilize the funds that they receive for scientific and educational purposes. The reports you have received from the academic community indicate the richness and variation of uses of royalty or licensing income for public health purposes. One impediment to meaningful evaluation of this process, however, is the lack of comprehensive data. Much of the information about the licensing practices of universities is not immediately transparent, nor are the uses of the funds derived from royalties or licensing as clear as possible. There are two

steps that could improve this situation. The NIH Director could convene a conference of affected parties that would permit compilation of a better set of data on these issues. Such a conference could also permit universities to learn from each other the best practices in place at sister institutions. In addition, we recommend that the pending Institute of Medicine Study of the Future of Academic Health Centers be asked to look at the role of technology transfer as part of its mandate.

In sum, we appreciate the partnership we have enjoyed with the NIH and its grantees. We believe that this partnership has produced tremendous public health benefits. We stand ready and willing to work with you and your colleagues to further advance the interests of patients and economic development by improving the technology transfer process.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Holmer", written in a cursive style.

Alan F. Holmer